

Applicants: Michael R. Rosen, et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 7

**REMARKS**

Reconsideration and allowance of the present application in view of the foregoing amendments and accompanying remarks are respectfully requested.

Claims 1-12 and 15-35 were pending in the subject application, with claims 4-8, 10, 12, and 17-31 withdrawn from consideration. By this Amendment, applicants have hereinabove canceled claims 4-8, 10, 12, and 17-31 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future. In addition, applicants have hereinabove amended claims 1, 9, 11, 15, and 32, and added new claims 36-42. Applicants maintain that amended claims 1, 9, 11, 15, and 32, and new claims 36-42, raise no issue of new matter and are fully supported by the specification as filed. Support for amended claim 1 may be found, in the specification, as originally filed, at, *inter alia*, page 3, line 17 through page 4, line 2; page 13, line 19 through page 14, line 9; and page 5, lines 20-21. Support for amended claim 9 may be found, in the specification, as originally filed, at, *inter alia*, page 13, lines 21-22. Support for amended claim 15 may be found, in the specification, as originally filed, at, *inter alia*, page 4, lines 3-10; and page 5, lines 20-21. Support for amended claim 32 may be found, in the specification, as originally filed, at *inter alia*, page 14, lines 16-20 and lines 7-9. Support for new claim 36 may be found in the specification as filed at, *inter alia*, page 14, lines 3-4. New claims 37 and 38 correspond to previously withdrawn claims 10 and 12 which the Examiner has stated are now rejoined. Support for new claims 39-41 may be found in the specification as filed at, *inter alia*, page 14, lines 7-15. Support for new claim 42 may be found in the specification as filed at, *inter alia*, page 3, lines

Applicants: Michael R. Rosen,<sup>r</sup> et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 8

3-6, and lines 12-15. In addition, applicants have hereinabove amended the specification to update the status of the cross referenced application.

Accordingly, upon entry of this Amendment, claims 1-3, 9, 11, 15-16, and 32-42 will be pending and under examination.

Applicants acknowledge that in the April 6, 2004 Office Action, the Examiner stated that claims 10, 12, 33, and 35 are rejoined with the elected species because there is no prior art of record against claims 9 and 32.

#### **Specification**

The Examiner stated that the disclosure is objected to because the status (e.g., pending, abandoned, patented US Patent No.) of the U.S. application listed in the cross reference is missing.

In response, applicants have hereinabove amended the specification in order to update the status of the cross reference.

#### **Claim Objections**

The Examiner stated that claims 9 and 32-35 are objected to because the status of the claims 9 and 32-35 is improper, and that the correct status for claims 9 and 32-35 is (previously presented).

In response, applicants note that the claims objected to are identified by the correct status in the listing of claims hereinabove.

Applicants: Michael R. Rosen, et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 9

**Claims Rejected Under 35 U.S.C. §112 (Second Paragraph)**

The Examiner stated that claims 32-35 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner further stated that claim 32 is rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections, and that the omitted structural cooperative relationships are: the connection between "compound" and the methods of "contacting". The Examiner stated that it is not clear whether the compound in the last sentence applies only to "co-culturing the cell" or to all the modes of delivery.

In response, applicants respectfully traverse the Examiner's rejection. However, without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 32 to more clearly define the claimed subject matter and to make clearer the cooperative relationship. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Claims Rejected Under 35 U.S.C. §102**

The Examiner rejected claims 15 and 16 under 35 U.S.C. §102(a) as allegedly being anticipated by Egdehl et al., (Cardiovascular Research 47:769-777, 2000) as evident by Xiao et al., (JBC, 269:19151-19156, 1994).

In response, applicants respectfully traverse the Examiner's

Applicants: Michael R. Rosen, et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 10

rejection. However, without conceding the correctness of the Examiner's position, but in order to expedite prosecution, applicants have hereinabove amended claim 15. Applicants note that Egde et al. do not teach a method of assaying wherein a cardiac myocyte is contacted *in vitro* with an amount of a composition comprising a nucleic acid encoding an ion channel effective to cause a sustainable beating rate, as recited in claim 15. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner rejected claims 15 and 16 under 35 U.S.C. 102(b) as allegedly being anticipated by Wheeler et al., (Anesthesiology 86:137-146, 1997) as evident by Xiao et al., (JBC, 269:19151-19156, 1994). The Examiner stated that Wheeler teaches studying the response of isolated rat heart cells to halothane, enflurane and isoflurane (page 137).

In response, applicants respectfully traverse the Examiner's rejection. However, without conceding the correctness of the Examiner's position, but in order to expedite prosecution, applicants have hereinabove amended claim 15. Applicants note that Wheeler et al. do not teach a method of assaying wherein a cardiac myocyte is contacted *in vitro* with an amount of a composition comprising a nucleic acid encoding an ion channel effective to cause a sustainable beating rate, as recited in claim 15. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner rejected claims 1, 2, 3, and 15 under 35 U.S.C. 102(b) as allegedly being anticipated by Kawana et al., (Comp. Biochem Physiol, 107C: 295-304, 1994). The Examiner stated that Kawana teaches a method of assaying whether an agent affects the beating rate of cardiac myocytes (pages 296-299).

Applicants: Michael R. Rosen, et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 11

In response, applicants respectfully traverse the Examiner's rejection. However, without conceding the correctness of the Examiner's position, but in order to expedite prosecution, applicants have hereinabove amended claims 1 and 15. Applicants note that Kawana et al. do not teach a method of assaying wherein a cardiac myocyte is contacted *in vitro* with an amount of a composition comprising a nucleic acid encoding an ion channel effective to cause a sustainable beating rate, as recited in claims 1 and 15. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

### **Third Supplementary Information Disclosure Statement**

In compliance with their duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following reference, which is listed on the accompanying form PTO-1449 (**Exhibit A**), and a copy of which is attached hereto as **Exhibit 1**.

1. U.S. Patent Application Publication No. 20020187948, Rosen et al., published December 12, 2002. (Exhibit 1)

This Third Supplementary Information Disclosure Statement supplements the Information Disclosure Statements filed by applicants on June 4, 2003; May 2, 2003; and October 3, 2002 in connection with the above-identified application.

Applicants believe that this reference does not anticipate or render obvious applicants' claimed invention. Applicants request that the Examiner review the listed reference and make it of record in the subject application.

Applicants: Michael R. Rosen, et al  
U.S. Serial No. 09/898,417  
Filed: July 3, 2001  
Page 12

This Third Supplementary Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(c). Accordingly, a check in the amount of ONE HUNDRED EIGHTY DOLLARS (\$180.00) is enclosed.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, apart from the enclosed \$180.00 fee for filing an Information Disclosure Statement, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22373-1450.

 6/4/04  
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1635 \$  
Docket No. 0575/65219-A/JPW/PJP/BJA

Application of: Michael R. Rosen et al.

Serial No.: 09/898,417

Examiner: B, Whiteman

Filed: July 3, 2001

Group Art Unit: 1635

For: A HIGH THROUGHPUT BIOLOGICAL HEART RATE THAT  
IS MOLECULARLY DETERMINEDCOMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 4, 2004

S I R:

Transmitted herewith is an amendment to the above-identified application.

☒ Small entity status of this application under 37 C.F.R. § 1.9 and § 1.27 has been established by a verified statement previously submitted.☐ a verified statement to establish small entity status under 37 C.F.R. § 1.9 and § 1.27 is enclosed.☐ No additional fee is required.

The filing fee is calculated as follows:

	NUMBER AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		NUMBER OF EXTRA CLAIMS PRESENTED		RATE		FEE	
							SMALL ENTITY	OTHER ENTITY	SMALL ENTITY	OTHER ENTITY
Total Claims	19	-	* 31	-	*** 0	x	\$9.00	\$18.00	- 0	
Independent Claims	2	-	** 6	-	*** 0	x	\$43.00	\$86.00	- 0	
Multiple Dependent Claims(s) Presented <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No							\$145.00	\$290.00	- 0	
For First Time:							TOTAL ADDITIONAL FEE \$ 0			

- \*If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 20, write "20" in this space.  
\*\*If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 3, write "3" in this space.  
\*\*\*If the difference between the "NUMBER AFTER AMENDMENT" and the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than "0", write "0" in the space.